

REMARKS

Entry of this amendment and reconsideration of this application, as amended, are respectfully requested.

Claim 71 has been amended to contain the feature that “the antibody is capable of binding to an epitope of FcγIIb comprising amino acids 27-30 of the amino acid sequence of FcγIIb according to SEQ ID NO:2”. Support for this amendment can be found, for example, at page 8, lines 22-24 of the specification. Claim 87 has been amended as suggested by the Examiner. Claim 112 has been canceled. No new matter has been introduced.

Claims 87 is rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Amendment to claim 87 by deleting “GB3” and “CE5” has obviated this rejection.

Claim 87 is also rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement.

The Examiner admits that the application provides the protein sequences of the variable light chain and heavy chains (SEQ ID NOs: 5 and 7) for antibody GB3, variable light and heavy chains (SEQ ID NOs: 9 and 11) for antibodies CE5. It is common knowledge in the art that the specificity of antibodies arises from their variable regions which are responsible for binding to an antigen. The constant regions are not important for antigen binding. An antibody is able to bind an antigen without its constant region (e.g. Fab fragments). Thus, a person of ordinary skill in the art is enabled to make and practice the subject matter set forth in claim 87 without the sequences of the constant regions.

Nonetheless, solely in order to advance prosecution and not in agreement as to correctness of the rejection of the claim, Applicants will deposit the cell lines which produce the antibodies GB3 and CE5 with the DSMZ (German Collection of Microorganisms and Cell

cultures), as suggested by the Examiner. Therefore, the enablement rejection of claim 87 should be withdrawn.

Claims 70-72, 77-78, 82-87, 92, 93, 106, 112, and 113 are rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabled. Applicants respectfully traverse.

Applicants would like to note that claim 77 has been withdrawn and claim 112 has been canceled, so this rejection does not apply to these two claims.

While the Examiner considers the invention as enabling for the antibody indicated on page 4 of the Office Action, he states that the specification, apart from that, does not contain sufficient information as to how antibodies other than the ones recited might be prepared and used. According to the Examiner, a skilled person cannot predict which additional CDRs would have to be paired together to form a functional antibody. The Examiner cites multiple references, including Rudikoff (PNAS 1982, vol. 79, pp. 1979-1983), Rader (PNAS 1998, 95: 8910-8915), and Koenig (U.S. 7,425,620) to support his argument.

However, the Examiner's argument is based on the wrong assumption. The Examiner apparently starts out from the assumption that a skilled person would clone various CDRs into an antibody. To the contrary, the present application (see, e.g., page 12, 1st paragraph and page 18, 1st paragraph of the specification) explicitly states that the antibodies of the presently claimed invention are obtained by immunizing a mammal with the immunogen. The antibodies are thereby produced by the immunized animal against the immunogen and then isolated from the extracted cells of the animal. Examples 2 and 3 of the present application describe in detail the immunization of a mouse with an immunogen of the invention and the subsequent analysis of the antibodies recovered from the cells as to their specificity towards FcγRIIb. This procedure is a routine method of antibody production (both monoclonal and polyclonal). Accordingly, the

skilled person need not carry out any undue experimentation to arrive at the presently claimed invention.

Therefore, this enablement rejection should also be withdrawn.

Claims 70-72, 77-80, 82-87, 92, 93, 106, 112 and 113 are rejected under 35 U.S.C. §102(e) for allegedly being anticipated by Koenig as evidenced by Fig. 5 of the instant specification and Veri et al. (Immunology, 2007, 121: 392-404). Applicants respectfully traverse.

Applicants first note that this rejection does not apply to claims 77 and 112, which have been withdrawn and canceled, respectively.

Koenig disclose an antibody clone 3H7 having the same CDR1 region of the light chain as inventive antibody GB3. In contrast to antibody GB3, 3H7 blocks the immune complex binding. The Examiner argues that, besides the blocking full-length antibodies 3H7 and 2B6, Koenig also discloses other antibody clones (1D5, 1F2, 2E1, 2H9 and 2D11; column 27) which also bind FcγRIIb with higher affinity than FcγRIIa. According to the Examiner, a later publication by the same inventors (Veri, Immunology, 2007, 121: 392-404) shows that both the Fab fragment of 3H7 and the other antibody clones 1D5, 1F2, 2E1, 2H9 and 2D11 prepared in Koenig do not interfere with immune complex binding to FcγRIIb.

However, it was not evident to a skilled person from the teaching of Koenig that the Fab fragment of 3H7, as shown later by Veri does not lead to a blocking of immune complex binding, especially since the Fab fragment of clone 2B6, which is also described in Koenig as a blocking full-length construct, still shows blocking in Veri. The results of Veri, to the contrary, merely show that not all Fab fragments have the same activity and do not lead to blocking.

Furthermore, it was not known which regions in FcγRIIb are suitable for non-blocking binding and, thus, activating the physiological function. The binding site on FcγRIIb of a claimed antibody has been specified by introducing the amino acid sequence of the CDE of FcγRIIb in amended claim 71. The CDE region comprising amino acids 27 to 30 of FcγRIIb according to amended claim 71 represents such a region. Koenig does not teach which CDE region of an antibody has to bind in order not to block immune complex binding.

In addition, there are no sequences disclosed for antibody clones 1D5, 1F2, 2E1, 2H9 and 2D11 which are described as non-blocking in Koenig (cf. column 112). Merely in column 26, lines 3-6, an antibody comprising the sequences having SEQ ID NOs: 2 and 4 is disclosed. SEQ ID NO:4 is the light chain which is different from the sequences of SEQ ID NOs:5 and 9 of the present application corresponding to the light chains of antibody GB3 and CE5, respectively.

Thus, Koenig does not teach the use of antibodies having the sequences of the presently claimed invention to obtain non-blocking antibodies. Also, as discussed above, Koenig does not disclose a binding site on FcγRIIb for non-blocking antibodies.

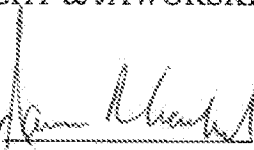
Therefore, Applicants submit that Koenig does not anticipate the presently claimed invention and this rejection must be withdrawn.

In view of the foregoing, allowance is respectfully requested.

The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0624, under Order No. NY-HUBR-1295-US.

Respectfully submitted

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